NOV 2 9 2000

K002986

510(k) Summary of Safety and Effectiveness
A.R.C. Low Bubble Turbo Needle

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Manufacturer:

A.R.C. Laser AG
St. Gallerstrasse 161
CH-8645 Jona
Switzerland

Submitter/Contact Person

Daniel Hoefer
A.R.C. Laser Corporation
2417 South 3850 West
Salt Lake City, UT 84120
TEL (801) 972 1311, FAX (801) 972 5251

Name of Device:

Trade Name: A.R.C. Low Bubble Turbo Needle
Classification Name: Unit, Phacofragmentation

Predicate Devices:

Alcon Turbosonics Limited Reuse Ultrasonic Tip (K981103), Storz Microflow Plus, Microflow Plus Angled, and Standard Angled Phacoemulsification Needles (K971439), and the Surgin High Performance Tips (K943102).

Description of Device:

The A.R.C. Low Bubble Turbo needle is a flared cylindrical titanium tip that is connected to the phacoemulsification handpice by the user using a special wrench (supplied). The phaco handpiece vibrates the needle at ultrasonic frequencies, resulting in fragmentation of cataractous lenses. Irrigation fluid flows into the eye between the needle's external surface and the internal surface of an irrigation sleeve. Emulsified lens material and irrigation fluid are aspirated from the eye through the lumen of the phaco needle. The needle is reusable and resterilizable.

Intended Use:

The A.R.C. Low Bubble Turbo Needle is intended as an accessory to a phaocoemulsification system, to be used in the phacofragmentation and aspiration of the cataractous crystalline lens.

Device Comparison:

The A.R.C. Low Bubble Turbo Needle is substantially equivalent to the following legally marketed predicate devices: The Alcon Turbosonics Limited Reuse Ultrasonic Tip (K981103), Storz Microflow Plus, Microflow Plus Angled, and Standard Angled Phacoemulsification Needles (K971439), and the Surgin High Performance Tips (K943102). The intended use, material composition, design, and reusability are all the same or equivalent. See chart below.

Substantially Equivalent Phaco Needles				
Parameter	K-number	Intended Use	Material Composition	Reuseability
A.R.C. Low Bubble Turbo Needle	Present	Phacoemul-sification of cataracts	Grade 5 titanium	Yes
Alcon Turbosonics Limited Reuse Ultrasonic Tip	981103	Phacoemul-sification of cataracts	Titanium (alloy unknown)	Yes
Storz Microflow Plus, Microflow Plus Angled, Standard Angled Phacoemul-sification Needle	K971439	Phacoemul-sification of cataracts	Titanium Ti-6Al-4V	Yes
Surgin High Performance Tips	K943102	Phacoemul-sification of cataracts	Titanium (alloy unknown)	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Daniel Hoefer
Regulatory Affairs Manager
A.R.C. Laser Corporation
2417 South 3850 West
Salt Lake City, UT 84120

Re: K002986
Trade Name: A.R.C. Low Bubble Turbo Needle
Regulatory Class: II
Product Code: 86 HQC
Regulation: 886.4670
Dated: September 22, 2000
Received: September 25, 2000

Dear Mr. Hoefer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002986

Device Name: A.R.C. LOW BUBBLE TURBO NEEDLE

Indications For Use:

Accessory to a phacoemulsification system, to be used in the phacofragmentation and aspiration of the cataractous crystalline lens.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daryl Kaufman

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002986

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format